

Health Sciences and Affiliated Teaching Hospitals Research Ethics Board Requirement for Proposal/Protocol with Submission for Ethics Review

The proposal should contain the following at minimum:

1. **Background and Rationale:** this should include a brief, referenced review of published work done around your research question of interest. Why is this area of research important? What are the knowledge/information gaps that remain to be addressed? If you have any pilot/preliminary results of your own, describe them here.
2. **Objectives / Hypotheses:** Clearly state your research question including the population to be studied, the exposures or interventions that will be compared and the primary outcome being assessed. Specific objectives should be listed and clearly defined so that the methods you describe can be related to these objectives.
3. **Methods / Research Plan should include descriptions of:**
 - a. Population to be studied: how will you identify and recruit participants? How long will they be in the study?
 - b. Include sample size and/or power calculations. This may also include providing an opinion on the feasibility of recruiting the sample and expectations for retention during study period
 - c. Describe study procedures clearly including the time commitment expected of participants.
 - d. List data that will be collected: this is often best done by adding, as an appendix, a draft of your data collection forms that would be used. This will permit reviewers to see that data you will collect, how you plan to code/classify the information collected and how you propose to handle personal and identifying information on participants.
 - e. Describe your plan for analysis of the information you collect. This will include your methods for making statistical comparisons.
 - f. Be sure that your methods clearly address your stated objectives.
 - g. What are your plans for secure and safe management and storage of information?
4. **Research Team:** List the known members of your research team. Briefly describe their roles and responsibilities for managing the study, the data you collect and their interactions with participants.
5. **Expectations:**
 - a. Where possible, suggest what results or outcomes you anticipate
 - b. What do you see as potential strengths and limitations of your proposed study

It is difficult to provide sufficient details for a study proposal in less than five pages and they should not be longer than 10 pages. While directed at the development of more sophisticated proposals, a useful detailed description of how to prepare a study proposal can be found under the Grants and Development tab at: http://www.queensu.ca/urs/resources-1#Writing_Winning_Proposals